REMARKS/ARGUMENTS

Reconsideration of this application and entry of the foregoing amendments are respectfully requested.

The specification has been amended to update the status of the parent case.

Claim 1 has been revised to define the invention with additional clarity. Specifically, claim 1 has been amended so as to be drawn to a method of screening a test mammal to determine whether said test mammal is at an increased risk for cancer. Non-elected claims 8-19 have been cancelled. That claims have been revised/cancelled should not be taken as an indication that Applicants agree with any view expressed by the Examiner. Rather, the revisions have been made merely to advance prosecution and Applicants reserve the right to pursue any deleted subject matter in a continuation application.

Claims 1, 4 and 5 stand rejected under 35 USC 103 as allegedly being obvious over Bundred et al in view of Poortmans et al. The rejection is traversed.

Bundred et al teaches that zinc alpha-2-glycoprotein ("ZnGP") is a serum and breast marker of apocrine activity. Bundred et al does not teach that individuals at an increased risk for cancer can be identified by assaying for the level of "ZnGP" in serum. The Examiner looks to Poortmans et al to cure the failings of Bundred et al.

Poortmans et al describes the use of immunological techniques to investigate presence of Zn-α_2-glycoprotein in biological fluids (including serum and urine) and kidney extract. Poortmanset al reports a low level of this protein in normal serum and a high level in urine – strenuous exercise is reported to enhance urinary excretion of this protein.

In rejecting the claims, the Examiner contends that it would have been obvious to substitute the serum immunoassay of Poortmans et al for the immunosassay of Bundred et al

"wherein it was found that ZAG is overexpressed in 50% of invasive breast carcinomas because it was known that ZAG is a soluble protein found in all body fluids and in particular Poortmans et al specifically teach that ZAG was found in plasma. Since ZAG is known as a secreted protein, it would be expected that overexpression of ZAG in the tumor would be associated with increased secreted protein in plasma."

The Examiner's contention overlooks the fact that nothing in the cited combination would have taught that an overproduction of ZAG in glandular tissue (e.g., breast tissue or prostate tissue) would necessarily have been reflected by a higher serum level. By way of example, breast epithelium produces milk – milk, however, is secreted into the lumen, not serum. In the prostate, ZAG produced by normal glands would not be expected to be available in the serum whereas disorganized malignant glands do not connect to the ejaculatory system and thus ZAG produced by malignant glands contributes to systemic ZAG levels.

Finally, it is only with hindsight that one would have combined Poortmans et al with Bundred et al, certainly, the references themselves would not suggested the combination.

In view of the above, reconsideration is requested.

Claims 1, 4 and 5 stand rejected under 35 USC 103 as allegedly being obvious over Lopez-Ortin et al, in view of Poortmans et al. The rejection is traversed.

Lopez-Ortin et al makes reference to the fact that ZAG accumulates in breast cyst fluid and that analysis of breast cancer tissues and secretions has revealed the existence of a significant percentage of mammary tumors that produce and secrete appreciable amounts of ZAG. As the Examiner appreciates, Lopez-Ortin et al does not teach assaying serum ZAG levels. The Examiner relies on Poortmans et al to cure that failing.

As pointed out above, the Examiner has not taken into account the fact that an overproduction of ZAG in, for example, breast tissue does not necessarily translate into an elevated serum level. Accordingly, nothing in the combination upon which the Examiner relies would have provided basis for a reasonable expectation of success in using serum levels of ZAG as a marker for increased cancer risk. Reconsideration is requested.

Claims 1 and 4-6 stand rejected under 35 USC 112, first paragraph, as allegedly being non-enabled. Withdrawal of the rejection is submitted to be in order in view of the above-noted claim amendments and comments that follow.

Claim 1 has been revised to more clearly indicate that the instant invention is a screening method that can be used to identify a test mammal that is at an increased risk of having cancer. While this revision is believed to address the Examiner's concerns (particularly given the Examiner's comments in the last paragraph of item 6 on page 8 of the Action), Applicants believe that it is important to note that it is an increase in ZAG that causes cachexia, not the reverse. It appears that the Examiner may have misunderstood the references cited on pages 6 and 7 of the Action as teaching that cachexia is the cause of elevated ZAG.

Reconsideration is requested.

Claims 1 and 4-6 stand rejected under 35 USC 112, first paragraph, as allegedly lacking written description. The rejection is traversed.

The Examiner's attention is directed to, for example, the paragraph bridging pages 23 and 24 where it is clear that the same technique (antigen capture immunoassay) was used to assay ZAG levels in the cancer patients and matched controls. Reconsideration is requested.

HALE et al
Appl. No. 09/998,923
November 7, 2005

This application is submitted to be in condition for allowance and a Notice to that effect is requested.

Respectfully submitted,

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